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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,824	12/03/2003	George Zabrecky	11352-004-999	5525

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,824	ZABRECKY, GEORGE	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) 45-51 is/are allowed.

6)☒ Claim(s) 1-8,10-15,17-34,36-41,43,44 and 52-56 is/are rejected.

7)☒ Claim(s) 9,16,35 and 42 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 0504.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-56 are presented for examination on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10-15, 17-34, 36-41, 43, 44, and 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted state of the art.

A first or second composition (or kit) for treating chronic liver disease, chronic HCV infection or non-alcoholic steatohepatitis comprising (within the first composition) glycyrrhizin (from licorice), schisandra extract, ascorbic acid (vitamin C), L-glutathione, silymarin (from milk thistle), lipoic acid, and d-alpha-tocopherol (vitamin E); or comprising (within the second composition) glycyrrhizin (from licorice), ascorbic acid (vitamin C), L-glutathione, and vitamin B-complex is claimed, as is a method of treating chronic liver disease, chronic HCV infection or non-alcoholic steatohepatitis via administering such compositions (via various routes) to a subject.

As readily admitted by Applicant, each of the instantly claimed ingredients (antioxidants) is well known in the prior art to be useful for effectively treating viral hepatitis (e.g., chronic HCV), and/or improving hepatic function, in a subject in need thereof - including via administration through various conventional routes such as orally and/or intravenously (parentally). Further, with respect to vitamin C and glutathione interactions, Applicant also readily admits that these components are well known in the art to beneficially effect each other *in vivo* in terms of improving hepatotoxicity (see, e.g., paragraphs [0024]-[0048]).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine various combinations of the instantly claimed ingredients (e.g., those that make up the first claimed composition/kit, as well as those that make up the second claimed composition/kit) for their known benefit since each is well known in the art for the same purpose (i.e., treating hepatitis/improving hepatic function) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Applicant's invention is predicated on an unexpected result, an unpredictable phenomenon highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the references that make up the admitted state of the art as taught within the instant specification (as discussed above) set forth before him/her. The result-effective adjustment of particular conventional working conditions (e.g., using oral, parental, and/or syringe infusion administration forms - as well as forming kits thereof; and/or determining an appropriate amount of at least one of the herbal ingredients therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the admitted teachings concerning the state of the art, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the admitted state of the art, especially in the absence of evidence to the contrary.

Applicant has reasonably disclosed/demonstrated that a composition (as well as appropriately defined kit claims) comprising particular amount ranges of the instantly claimed combination of 7 ingredients that make up the first recited composition (see, e.g., claims 9, 35, 45), and a composition (as well as appropriately defined kit claims) comprising particular amount ranges of the instantly claimed combination of 4 ingredients that make up the second recited composition (see, e.g., claims 16, 42, 45), are improved therapeutic formulations (over the art) with respect to treating the instantly claimed hepatic disorders/diseases.

Accordingly, claims 9, 16, 35, 42, and 45 are deemed free of the art.

Claim Objections

Claims 9, 16, 35, and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 45-51 are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1655